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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,609	12/22/2003	Ronald L. Ream	112703-315	7553

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,609

Applicant(s)

REAM ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10-12,14-18,23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10-12,14-18,23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendment filed 12/29/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "ingested principally through the gastrointestinal region of the individual" in claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rejected in the use of the phrase "the chewing gum including less than the typical amount of stimulant that is swallowed by the individual to achieve the effect".

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The specification does not define what amount of the stimulant is "the typical amount" swallowed to achieve an effect.. In this case, the claims do not reasonably appraise those skilled in the art of the scope of the claimed method. See also the Decision on Appeal dated 09/10/04 of application 09/286,818 at pages 4-6.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7, 8, 10-12, 14-18, 23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Song et al. US 6,586,023.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Song discloses a chewing gum composition comprises stimulant, such as caffeine, to be used to enhance performance (column 4, lines 25-67). The caffeine-containing chewing is to be chewed in ten minutes or less before the performance (column 7, lines 67 through column 8, lines 1-4). The daily dosage is two pieces every four hours but not more than four to five times a day (column 8, lines 20-23). Song further discloses the chewing gum composition allows for delivery of caffeine levels on the order of that found in a cup of coffee (column 4, lines 59-62).

It is noted that Song does not teach the chewing gum creates a saliva content of stimulant of approximately 15 to about 440 ppm. However, it is the examiner's position that the chewing gum composition of Song would create a similar saliva content of stimulant because Song teaches the same chewing gum composition, the same chewing time, and the same dosage regiment for the same purpose, namely, to enhance alertness performance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7, 8, 10-12, 14-18, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudas et al. WO 98/23165.

Gudas teaches method of controlling release of chewing gum having caffeine as a stimulant effective to increase energy, and reduce drowsiness (see abstract and page 4, lines 13-19). The rate of release is disclosed in page 5, lines 9-18. Gudas is silent as to the teaching of the saliva content of the stimulant (claims 11 and 25), however, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation modify the chewing gum composition taught by Gudas to obtain a similar saliva content of the stimulant because Gudas discloses the use of caffeine in the same form, e.g., chewing gum; and for the same purpose, namely, to increase energy and reduce drowsiness.

Regarding to claims 14 and 18, the reference differs from the claimed invention by not specifically teaching the chewing time before action is taken. However, it would have been obvious for one of ordinary skill in the art to chew the chewing gum taught by Gudas prior to taking any athlete action to enhance alertness and to increase energy, because Gudas teaches a chewing gum composition containing caffeine to reduce drowsiness and increase energy.

Response to Arguments

Applicant's arguments filed 12/29/04 have been fully considered but they are not persuasive.

Applicant argues that the specification at page 2, lines 11-13 provides sufficient support for the limitation "ingested principally through the gastrointestinal (GI) region of the individual" in claim 7. However, page 2, lines 11-13 discloses the background of the invention, and generally states that drug absorption through oral administration usually occurs due to the transport of cells across the membranes of the epithelial cells within the GI tract. Nowhere does the specification provide a specific guidance that the claimed chewing gum composition is ingested principally through the GI region of the individual. To the contrary, applicant's specification at page 4, lines 9-13, discloses by chewing the gum, the medicament or agent is released from the chewing gum, *forcing the agent or medicament directly into the systemic system of the individual through the oral mucosa contained in the buccal cavity*. Accordingly, drug absorption is through the membrane of the oral mucosa. Thus, the 11, 1st paragraph rejection over claim 7 is maintained.

Applicant argues that one skilled in the art would recognize that the chewing gum as claimed includes an amount of stimulant, such as caffeine, that is less than an amount of the same stimulant as swallowed, such as via oral administration in the form of a typical tablet or capsule. However, the language of claim 7 is not as clear as the remarks. Claim 7 recites "the chewing gum including less than the typical amount of stimulant that is swallowed by the individual". What typical amount? How can one

skilled in the art determine the "typical" amount? Accordingly, the 112, 2nd paragraph rejection over claim 7 is maintained.

Applicant argues that the Patent Office has not demonstrated that the subject matter relied on for the anticipation rejection was not new matter added to the continuation-in-part application. Thus, the earlier effective filing date of the present application antedates Song and renders Song unavailable for use as prior art under § 102(e). Contrary to the applicant's argument, Song is relied upon as a prior art under § 102(e) in view of the provisional application dated 12/15/1998 as a priority date. As a result of the availability of Public PAIR, the office is no longer required to provide copy of a provisional application relied upon to give prior art effect under 35 U.S.C. § 102(e). Applicant can access the provisional application No. 60/112,378 via PAIR at <http://portal.uspto.gov/external/portal/pair>. Accordingly, Song is available for use as prior art under § 102(e).

Applicant argues that Gudas does not teach or suggest chewing and continuing to chew the chewing gum, thus causing the stimulant to adsorb through the oral cavity as claimed. Gudas relates to masking the unpleasant taste of caffeine by a coating and not stimulant delivery through the oral mucosa. Therefore, one skilled in the art would recognize that Gudas fails to render obvious the claimed invention. However, it is noted that, first, Gudas teaches the same composition for the same active agent, namely, a chewing gum composition to deliver caffeine (see abstract); second, Gudas teaches a method for controlling the release of caffeine for the same purpose, namely, effectively to increase energy, and reduce drowsiness (see abstract; and page 4, lines 13-19).

Thus, it would have been obvious for one skilled in the art to chew and continue chewing to achieve the effect of caffeine, e.g., increasing energy. Accordingly, the 103(a) rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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